

	<b>TEXAS DEPARTMENT OF STATE HEALTH SERVICES</b> P.O. Box 149347 • Austin, Texas 78714-9347 • 1-888-963-7111	F14-14058 August 2016
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## Requests for Residual Newborn Screening Specimens and/or Data—Research and QA/QC purposes

Consistent with Texas state law (Texas Health & Safety Code Sec. 33.018), DSHS has a strict policy (CD2010.01) regarding allowable uses of residual newborn screening blood spots and associated data. This form must be completed for all proposed releases of newborn screening specimens and/or data that are for Quality Assurance/Quality Control (QA/QC) and/or research as the terms defined at Texas Health & Safety Code Sections 33.018(b)(5), 33.018(c)(3), and 33.018(c-1)\*.

### Newborn Screening Blood Spot and Data Use Policy

- Quality Assurance/Quality Control uses related to public health testing equipment and supplies (as specified in the policy referenced above) are reviewed by DSHS Management and the DSHS IRB to determine if the uses are appropriate, scientifically sound, and allowable under the policy.
- All proposed public health\*\* research uses are reviewed by DSHS Management and the DSHS IRB. The IRB is tasked with ensuring the protection of the safety, rights, and welfare of human participants involved in the project (this includes studies on specimens taken from a person).
- If a project is approved, the requester may only use the blood spots and/or data in the way, and for the time period, specified in the final IRB-approved project description.

## Overview of Request for Use Review Process

1. Requestor contacts the DSHS Program Contact for the Program most appropriate for the proposed study. See [alphabetical list of programs and contacts](#).
2. Requestor completes the *Request for Residual Newborn Screening Specimens and/or Data form* (page 2).
3. Requestor submits request by email to both [NewbornScreeningLab@dshs.state.tx.us](mailto:NewbornScreeningLab@dshs.state.tx.us), and the DSHS Program Contact.
4. A DSHS Newborn Screening liaison will contact requestor to verify request receipt and to attain additional needed information.
5. If the request meets the established criteria, the laboratory liaison will forward the request to the appropriate DSHS Program Contact, DSHS Laboratory Director and/or Specialized Health Services Director (as appropriate) for approval.
6. If request is approved by the Section Director(s), DSHS Program contact will coordinate with the requestor for the completion and /or submission of any required documentation for the DSHS IRB application.
7. IRB will review and make a determination. If request is not approved by the IRB, the requester will be notified. If approved by IRB, request will be forwarded to the Research Executive Steering Committee (RESC)\*\*\* for review and approval. The RESC will also determine if review and approval by the DSHS Commissioner is required.
8. If approval from the Commissioner or designee is required, the DSHS Program Contact will submit an action memorandum to request review and a decision.
9. The DSHS Program Contact will notify the requestor of the final decision or of any changes required prior to approval.

## Notes

\* QA/QC uses expressly allowed under HSC Sec. 33.018(b)(6), (b)(7), (b)(8), and (c)(2) are not within the scope of this form.

\*\* Public health purpose as defined in statute (Texas Health & Safety Code Section 33.018) relates to cancer, a birth defect, an infectious disease, a chronic disease, environmental exposure, or newborn screening.

\*\*\* The RESC is currently comprised of DSHS officials including the State Epidemiologist, Chief Operating Officer General Counsel, and one or more Assistant Commissioners. The DSHS Commissioner may participate in this group at any time.

## Contacts and More Information

- **Email DSHS Newborn Screening Laboratory:** [NewbornScreeningLab@dshs.state.tx.us](mailto:NewbornScreeningLab@dshs.state.tx.us)
- **Fax:** 512-776-2594    **Phone:** 512-776-7430
- **DSHS Newborn Screening website:** <http://www.dshs.state.tx.us/lab/newbornscreening.shtm>
- **DSHS IRB website:** <http://www.dshs.state.tx.us/irb/Default.shtm>.

### Request for Residual Newborn Screening Specimens and/or Data Form

<b>Requestor</b>	<b>Name:</b>		
	<b>Title:</b>		
	<b>Mailing Address:</b>		
	<b>City, State, Zip:</b>		
	<b>Phone #:</b>		
	<b>Email Address:</b>		
<b>Project Contact</b>	<b>Name &amp; Title</b> (if different than requestor):		
	<b>Phone #:</b>		
	<b>Email Address:</b>		
	<b>Organization/Institution Name:</b>		
<b>Project Overview</b>	<b>Title of Study</b> (if available):		
	<b>Funding Source</b> (Is the project federally funded?)		
	<b>Summary of Project:</b> Include how the project supports a public health** or QA/QC purpose. Explain why newborn screening specimens and or data are necessary.		
<b>Request Information</b>	<b>Approximate # of residual blood spot specimens requested:</b> Also include frequency of delivery, if applicable.		
	<b>Sub-population specifications:</b> (e.g. 1 <sup>st</sup> screen 24-48 hours after birth, 2 <sup>nd</sup> screen 7 days after birth or more, etc.)		
	<b>Specific data field(s) requested</b> (if applicable): Include a brief explanation of how each field will be used and/or why each field is critical to the project outcome.		
	<b>Date specimens and/or data are needed:</b>		



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August 2016

**DSHS Internal Use Only**

Program Reviewer Name: Click here to enter text.

DSHS Division & Section: Click here to enter text.

Title: Click here to enter text.

Telephone: Click here to enter text.

Summary: Click here to enter text.

Recommendation: Click here to enter text.

Laboratory Operations Unit Review Name: Click here to enter text.

DSHS Division & Section: Click here to enter text.

Title: Click here to enter text.

Telephone:

Summary: Click here to enter text.

Recommendation: Click here to enter text.

Laboratory Services Section Review Name: Click here to enter text.

DSHS Division & Section: Click here to enter text.

Title: Click here to enter text.

Telephone: Click here to enter text.

Summary: Click here to enter text.

Recommendation:

Specialized Health Service Review (if applicable) Name: Click here to enter text.

DSHS Division & Section: Click here to enter text.

Title: Click here to enter text.

Telephone: Click here to enter text.

Summary: Click here to enter text.

Recommendation: Click here to enter text.